

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

22 Jun 2026

### Effect of intravenous aminophylline on post- spinal anesthesia headache in women under cesarean section

#### Protocol summary

##### Study aim

The effect of intravenous aminophylline on post- spinal anesthesia headache in women under cesarean section

##### Design

Clinical practice with control and intervention group, with parallel groups, simple randomized triple blind

##### Settings and conduct

In this clinical trial study in Ninth Diabetes Hospital in 1397, each patient was enrolled by an anesthetist after an appointment and then examined for exit criteria. Then, the researcher will prescribe one of the two drugs based on the previously prepared randomized form and the nurse is not known to have any type of drug. For patients who are eligible, the pain questionnaire is filled up before and after 24 hours.

##### Participants/Inclusion and exclusion criteria

Entry Requirement: Satisfaction to participate in the study Subjected to cesarean section with spinal anesthesia No history of sensitivity to aminophylline or other xanthine derivatives with accurate history from them. Age 45-18 years Lack of history of migraine headaches, coagulation disorders, gestational toxicity, diabetes, seizure, smoking and narcotics, and cardiovascular diseases Conditions for not admitting to study: Performing a retinal anxiety Unwillingness to cooperate in the study General anesthesia Use of xanthine derivatives during the study

##### Intervention groups

Patients in both intervention and control groups randomly received aminophylline and normal serum saline (0.09%) and normal serum saline (0.09%).

##### Main outcome variables

Headache

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20180607040003N1**

Registration date: **2018-09-03, 1397/06/12**

Registration timing: **retrospective**

Last update: **2018-09-03, 1397/06/12**

Update count: **0**

##### Registration date

2018-09-03, 1397/06/12

##### Registrant information

###### Name

Hosein Bayesteh

###### Name of organization / entity

###### Country

Iran (Islamic Republic of)

###### Phone

+98 51 5224 3329

###### Email address

hosein\_bayesteh@yahoo.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2018-04-21, 1397/02/01

##### Expected recruitment end date

2018-08-21, 1397/05/30

##### Actual recruitment start date

2018-04-21, 1397/02/01

##### Actual recruitment end date

2018-04-21, 1397/02/01

##### Trial completion date

empty

##### Scientific title

Effect of intravenous aminophylline on post- spinal anesthesia headache in women under cesarean section

##### Public title

Effect of intravenous aminophylline on post- spinal

anesthesia headache in women under cesarean section

### **Purpose**

Treatment

### **Inclusion/Exclusion criteria**

#### **Inclusion criteria:**

Satisfaction to participate in the study Subjected to cesarean section with spinal anesthesia No history of sensitivity to aminophylline or other xanthine derivatives with accurate history from them. Age 45-18 years Lack of history of migraine headaches, coagulation disorders, gestational toxicity, diabetes, seizure, smoking and narcotics, and cardiovascular diseases

#### **Exclusion criteria:**

Performing a retinal anxiety Unwillingness to cooperate in the study General anesthesia Use of xanthine derivatives during the study

### **Age**

From **18 years** old to **45 years** old

### **Gender**

Female

### **Phase**

1

### **Groups that have been masked**

- Participant
- Care provider
- Outcome assessor

### **Sample size**

Target sample size: **70**

Actual sample size reached: **70**

### **Randomization (investigator's opinion)**

Randomized

### **Randomization description**

Available sampling from all women candidates for cesarean section with spinal anesthesia referred to Razi Torbat Heydarieh Hospital and Allameh Bhlol Gonabadi Hospital in Gonabad city, after being eligible for inclusion criteria by random allocation method using blocks Reversal, so that the number 1 as an intervention group (the group receiving aminophylline 3 mg based on the ideal body weight and 500 ml normal saline 0.9% venous) and the number 2 as the control group (receiving group 500 C C is considered to be 0.9% venous saline), and 4-block blocks (eg 2121) in the theme

### **Blinding (investigator's opinion)**

Double blinded

### **Blinding description**

In this study, the patients in the intervention group, after obtaining informed consent and entering the study, are not aware of which amniotic fluid injectable serum are available. Also, the clinical caregiver of the intervention group is unaware. Only the researcher has prepared the serum and the name of the patient in the intervention group and It will provide control to the clinical care provider for infusion, as well as assessing the outcome of the pain, the clinician will do without the knowledge of the intervention and control group.

### **Placebo**

Used

### **Assignment**

Parallel

### **Other design features**

### **Secondary Ids**

empty

### **Ethics committees**

1

#### **Ethics committee**

##### **Name of ethics committee**

Gonabad University of Medical Sciences

##### **Street address**

Asian Roadside Border

##### **City**

gonabad

##### **Province**

Razavi Khorasan

##### **Postal code**

9691793718

#### **Approval date**

2017-12-17, 1396/09/26

#### **Ethics committee reference number**

IR.GMU. REC.1396.62

### **Health conditions studied**

1

#### **Description of health condition studied**

Headache

#### **ICD-10 code**

G44

#### **ICD-10 code description**

Other headache syndromes

### **Primary outcomes**

1

#### **Description**

Headache

#### **Timepoint**

24h

#### **Method of measurement**

observation

### **Secondary outcomes**

empty

### **Intervention groups**

1

#### **Description**

Intervention group: Headache before giving aminophylline in the aminofilin dose group. In this study, 3 cc per kg body weight of the drug are given at the diagnosis of the headache, and after an hour the patient

is examined by the doctor and the healing It is recorded.

**Category**

Treatment - Drugs

**2**

**Description**

Control group: For patients in the control group, only 500 cc normal saline 0.9% intravenous infusion is infused over 2 hours.

**Category**

Treatment - Drugs

**Recruitment centers**

**1**

**Recruitment center**

**Name of recruitment center**

Women's Hospital, 9day

**Full name of responsible person**

hoseyn bayeste

**Street address**

Razi Ave,Ferdowsi Blv

**City**

Torbat heydarieh

**Province**

Razavi Khorasan

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9516915169

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**Email**

m.eshaghzadeh93@gmail.com

**Sponsors / Funding sources**

**1**

**Sponsor**

**Name of organization / entity**

Gonabad University of Medical Sciences

**Full name of responsible person**

hoseyn bayesteh

**Street address**

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**Grant name**

**Grant code / Reference number**

**Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Gonabad University of Medical Sciences

**Proportion provided by this source**

100

**Public or private sector**

Public

**Domestic or foreign origin**

Domestic

**Category of foreign source of funding**

empty

**Country of origin**

**Type of organization providing the funding**

Academic

**Person responsible for general inquiries**

**Contact**

**Name of organization / entity**

Gonabad University of Medical Sciences

**Full name of responsible person**

hoseyn bayeste

**Position**

Master student of nursing

**Latest degree**

Bachelor

**Other areas of specialty/work**

Nursery

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**Contact**

**Name of organization / entity**

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**Full name of responsible person**

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**Position**

Master student of nursing

**Latest degree**

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**Other areas of specialty/work**

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**Position**

Master student of nursing

**Latest degree**

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**Other areas of specialty/work**

Nursery

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**Postal code**

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**Email**

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**Sharing plan**

**Deidentified Individual Participant Data Set (IPD)**

Undecided - It is not yet known if there will be a plan to make this available

**Study Protocol**

Undecided - It is not yet known if there will be a plan to make this available

**Statistical Analysis Plan**

Undecided - It is not yet known if there will be a plan to make this available

**Informed Consent Form**

Undecided - It is not yet known if there will be a plan to make this available

**Clinical Study Report**

Undecided - It is not yet known if there will be a plan to make this available

**Analytic Code**

Undecided - It is not yet known if there will be a plan to make this available

**Data Dictionary**

Undecided - It is not yet known if there will be a plan to make this available